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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Martin Brouillette

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EXAMINER

HALL, DEANNA K

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

10/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,267	Applicant(s) BROUILLETTE ET AL.	
	Examiner DEANNA K. HALL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-8, 10, 15-32, 36, 37, 39, 40 and 42-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-8, 10, 15-32, 36, 37 and 39-40, 42-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on June 15, 2009.
2. Claims 4-8, 10, 15-32, 36-37, 39-40 and 42-45 are pending in this application.
3. In view of applicant's remarks, the 112, second paragraph rejection of claims 39 and 40 is withdrawn.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross et al. (US 5,261,601) ("Ross") in view of Bellhouse et al. (US 5,630,796) ("Bellhouse").**

Ross discloses a device and method for needless injection of a liquid substance, the method comprising: generating droplets of the liquid substance C4 L28-46; directing and accelerating the droplets at a velocity sufficiently high to inject the droplets into the target biological tissue C7 L10-19. In Ross the droplets of liquid substance are generated by actuating a transducer to force liquid from a reservoir 4 through at least

one micro-orifice of a perforated membrane 13 to produce a jet of the liquid substance that transforms into a stream of droplets C4 L28-46.

Ross does not directly disclose generating the droplets of liquid substance by injecting a pressurized gas from a pressurized source into a liquid reservoir. Bellhouse, in the analogous art, teaches forcing the liquid from a reservoir not by a transducer but by a gas cartridge C1 L35-44. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Ross with the energy mechanism (injecting pressurized gas) as taught by Bellhouse for moving the liquid substance through the perforated membrane.

Bellhouse teaches a source of pressurized gas and a valve for connecting the source of pressurized gas to the reservoir of the liquid substance, opening the valve causes pressurized gas from the source to be supplied to the reservoir C4 L62-C5 L4, Fig. 6.

6. Claims 39-40, 4-8, 10, 15-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross in view of Bellhouse et al. (US 5,630,796) ("Bellhouse").

Ross discloses a device and method for needless injection of a liquid substance, the method comprising: generating droplets of the liquid substance C4 L28-46; directing and accelerating the droplets at a velocity sufficiently high to inject the droplets into the target biological tissue C7 L10-19. In Ross the droplets of liquid substance are generated by actuating a transducer to force liquid from a reservoir 4 through at least one micro-orifice of a perforated membrane 13 to produce a jet of the liquid substance that transforms into a stream of droplets C4 L28-46. The perforated membrane 13 or

Ross that contains at least one micro-orifice is comprised of a metallic material C2 L32-33.

However, Ross further does not directly disclose supplying and conveying the droplets into the jet of gas and guiding the jet of gas through a channel towards the surface of the target biological tissue. Bellhouse, in the analogous art, teaches entraining a therapeutic agent in a supersonic gas flow C1 L30-44 and guiding the jet flow through a channel Fig. 1 to the surface of the biological tissue. Thus, the pressure in Bellhouse coming from a pressurized gas reservoir 11. The jet of gas in Bellhouse is guided along a face of the perforated membrane on a side opposite to the liquid reservoir. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the pressure source of Ross with the pressurized gas of Bellhouse for generating enough pressure to create an atomized spray of liquid droplets.

Bellhouse further discloses generating the high velocity jet of gas by supplying pressurized gas from a gas reservoir 11 to a convergent-divergent 35, 37, Fig. 1. The jet of gas is an inert gas C5 L46-55.

The convergent-divergent of Bellhouse further comprises a throat, Fig. 1 and an intermediate chamber 25. The intermediate chamber 25 is between the pressurized gas supply and the inlet of the convergent-divergent Figs. 1, 5, 6 with a valve to control the supply of pressurized gas to the intermediate chamber and from the intermediate chamber to the convergent-divergent C14 L26-35, C5 L53-67. This intermediate chamber 25 can also be considered to be interposed between the pressurized gas

supply and the liquid reservoir 28. Bellhouse further discloses the liquid chamber 28 having a movable wall or burstable membrane to displace the liquid by means of a piston C6 L53-67. The valve releasing the gas flow to the convergent-divergent is a mechanical valve comprising a piston, spring or plunger C6 L53-67.

Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate electronic rather than mechanical valves, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

7. Claims 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross in view of Garitano et al. (US 6,689,095) (“Garitano”).

Ross discloses a device and method for needless injection of a liquid substance, the method comprising: generating droplets of the liquid substance C4 L28-46; directing and accelerating the droplets at a velocity sufficiently high to inject the droplets into the target biological tissue C7 L10-19. In Ross the droplets of liquid substance are generated by actuating a transducer to force liquid from a reservoir 4 through at least one micro-orifice of a perforated membrane 13 to produce a jet of the liquid substance that transforms into a stream of droplets C4 L28-46.

Ross does not directly disclose supplying pressurized gas to a gas-tight chamber and applying by means of the pressurized gas a pressure to a slidable piston interposed between the gas chamber and a liquid reservoir to force the liquid out into a stream of

droplets. The energy mechanism in Ross is the activation of the transducer but Garitano, in the analogous art, teaches supplying compressed gas to a gas cartridge by an air compressor attached to the housing through a tube C2 L53-58, C4 L48-50 and applying pressure from the pressurized gas 70 to a piston 50 that forces the liquid from the liquid reservoir 33, Fig. 1. Garitano also teaches a valve 110 to control the pressure put on the piston from the gas chamber. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Ross with the energy mechanism as taught by Garitano for controlling the liquid injection.

Response to Arguments

8. Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that Ross should not be modified with Bellhouse because Ross never intends to have the droplets injected into the lungs of a patient. This argument is not persuasive. An object of Ross is to have a vibrating perforate membrane having enhanced performance in which the rate at which liquid is dispensed is improved C2L5-8. Thus, introducing a pressurized gas source of Bellhouse would be likely to meet this objective. Further, applicant's claims state "a velocity sufficiently high to inject the droplets of the liquid substance into the target biological tissue." This velocity in itself is met by Ross in that Ross also injects the droplets into the target tissue when the droplets are inhaled into the lungs of a patient.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEANNA K. HALL whose telephone number is (571)272-2819. The examiner can normally be reached on M-F 9:00am-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deanna K. Hall/

Examiner, Art Unit 3767

10/7/09

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767